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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/090,827	03/06/2002	Francois Bertelli	A0000179-C1-66-MG	6882

7590 02/26/2003

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EXAMINER

WILDER, CYNTHIA B

ART UNIT	PAPER NUMBER
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1637

DATE MAILED: 02/26/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.
10/090,827

Applicant(s)
BERTELLI et al.

Examiner
Cynthia B Wilder

Art Unit
1637



-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on Aug 23, 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-5 is/are pending in the application.
- 4a) Of the above, claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-5 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
*See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s). 6 6) ☐ Other:

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DETAILED ACTION

Specification

1. The specification is objected to because of the following informalities:
 - (a) The sequence identifier recited as "SEQ ID No" at pages 3, 4, 7, 16-18, 20, 21, 24, 26 and 29 and the sequence identifier recited as "SEQ ID N" at page 6 is improper. It is suggested changing "SEQ ID No" and "SEQ ID N" to "SEQ ID NO:" (See MPEP 2422.03).
Appropriate correction is required.

Claim Rejections - 35 USC § 102(a)

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the Applicant for a patent.

3. Claims 1, 3, 4, and 5 are rejected under 35 U.S.C. 102(a) as being anticipated by Brown et al. and Gee et al. (*Journal of Biological Chemistry*, Vol. 273, No. 39, pp 25458-465, September 25, 1998). Regarding claims 1, Brown and Gee teach a method for screening of a ligand which binds a cerebral cortical voltage-dependent calcium channel $\alpha_2\delta-1$ subunit, the method comprising the steps of: contacting a secreted soluble recombinant calcium channel $\alpha_2\delta-1$ subunit polypeptide with a ligand of interest and a labeled compound which binds the $\alpha_2\delta-1$ subunit page 25460, col. 1, lines 2-7, page 25462, col. 2, lines 6-13); and measuring the level of binding of the labeled compound to

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the $\alpha_2\delta$ -1 subunit (Abstract and page 25461, subsection "Miscellaneous Methods" entire paragraph. See also Fig. 2 and legend, page 26462.) Therefore, the reference of Brown and Gee meets all the claimed limitation of claim 1.

4. Regarding claims 3-5, Brown and Gee teach a method according to claim 1 and further teach a primary sequence of the porcine cerebral cortical voltage-dependent calcium channel $\alpha_2\delta$ -1 subunit cDNA (Figure 1, page 25459) comprising sequences that are identical to the sequences of SEQ ID NOS: 6-9. Brown and Gee additionally teach mutant forms of the cDNA sequence which resulted in secreted soluble recombinant calcium channel $\alpha_2\delta$ -1 subunits (see Figure 2, page 25462). Therefore, the reference of Brown and Gee meets all of the claimed limitations of claims 3-5.

Claim Rejections - 35 USC § 103(a)

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) a patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

6. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and

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invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

7. Claim 2 is rejected under 35 U.S.C. 103(a) as being unpatentable over Brown and Gee as applied to claims 1, 3-5 above and further in view of Holland et al. (Analytical Biochemistry, November 1994). Regarding claim 2, Brown and Gee teach a method of screening of a ligand which bind the cerebral cortical voltage-dependent calcium channel $\alpha_2\delta$ -1 subunit comprising the steps of contacting a secreted soluble recombinant calcium channel $\alpha_2\delta$ -1 subunit polypeptide with a ligand of interest; and a labeled compound which binds the $\alpha_2\delta$ -1 subunit; and measuring the level of binding of the labeled compound to the $\alpha_2\delta$ -1 subunit.

The method of screening of Brown and Gee differs from that of the claim invention in that the reference does not expressly teach wherein the step of contacting and said binding is in a well of a flashplate.

Holland et al. teach a screening method of ligands using a flashplate assay wherein the contacting and binding is in the wells of a flashplate (see abstract). Holland et al. teach that the key feature of the flashplate binding assay is its simplicity. Holland et al. states that in essence, it comprises the addition of the radioligand and test compound, incubation and measurement and is convenient for screening compounds interacting at a receptor or quantitative receptor binding studies (page 517, last four lines bridging page 518, line 1). Holland further adds that no separation or washing steps are involved and this simplicity makes the assay more amenable to automation and

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thus allows for a more robust assay. (page 517, col. 2, third paragraph; Discussion). Therefore, it would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to have been motivated to have modified the ligand screening method of Brown and Gee by incorporating a flashplate assay as disclosed by Holland et al. One of ordinary skill in the art would have been motivated to do so for numerous advantages taught by Holland et al. that a flashplate assay is more simpler, more convenient and more robust for screening compounds interacting at a receptor or quantitative receptor binding studies and is more amendable to automation.

Conclusion

8. No claims are allowed.
9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Examiner Cynthia Wilder whose telephone number is (703) 305-1680. The examiner can normally be reached on Monday through Thursday from 9:30 am to 6:30 pm and on Friday from 9:30 am to 1:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion, can be reached at (703) 308-1119. The official fax phone number for the Group is (703) 308-4242. The unofficial fax number is (703) 308-8724.

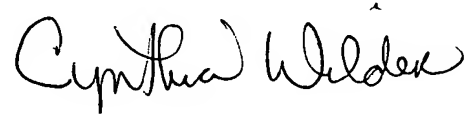
Any inquiry of a general nature or relating to the status of this application or proceeding should be directed the Group's receptionist whose telephone number is (703) 308-0196.

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cbw
February 24, 2003

A handwritten signature in cursive script, reading "Cynthia B. Wilder". The signature is written in black ink and is positioned above the printed name.

Cynthia B. Wilder, Ph.D.
Patent Examiner
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